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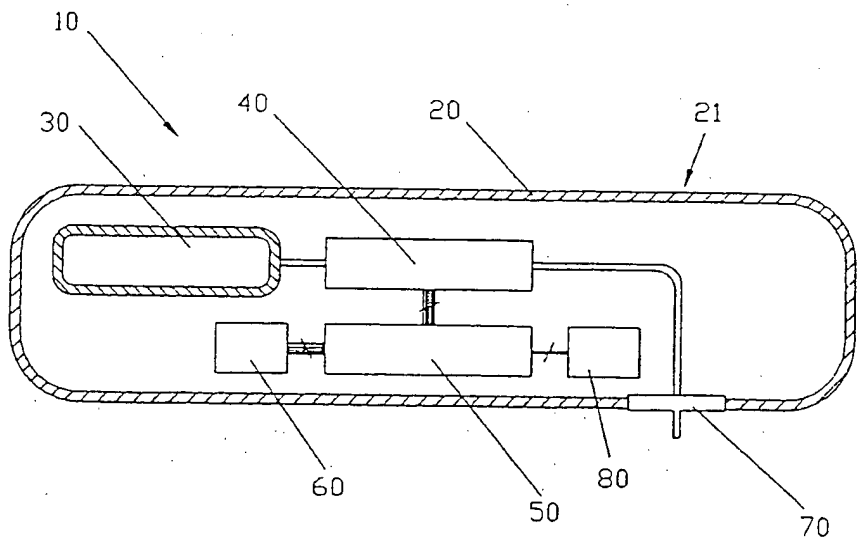

(57) Abstract: A device for delivering a fluid to a patient, including an exit port, a dispenser for causing fluid from a reservoir to flow to the exit port, a local processor programmed to cause a flow of fluid to the exit port based on flow instructions from a separate, remote control device, and a wireless receiver connected to the local processor for receiving the flow instructions. The device also inlcudes a housing free of user input components fro providing flow instructions to the local processor, in order to reduce the complexity and costs of the device so that the device lends itself to being disposable in nature. A system and a kit are also described that include the fluid delivery device, a separate, remote control device, and accessories for transcutaneous delivery of fluid medications. Methods of utilizing the fluid delivery device to infuse fluid medications are additionally disclosed.

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driven dispensers or transdermal patch technologies. Bolus injections often imperfectly match the clinical needs of the patient, and usually require larger individual doses than are desired at the specific time they are given. Continuous delivery of medicine through gravity feed systems compromise the patient's mobility and lifestyle, and limit the therapy to simplistic flow rates and profiles. Transdermal patches have special requirements of the medicine being delivered, particularly as it relates to the molecular structure, and similar to gravity feed systems, the control of the drug administration is severely limited.

(06) Ambulatory infusion pumps have been developed for delivering liquid medicaments to a patient. These infusion devices have the ability to offer sophisticated fluid delivery profiles accomplishing bolus requirements, continuous infusion and variable flow rate delivery. These infusion capabilities usually result in better efficacy of the drug and therapy and less toxicity to the patient's system. An example of a use of an ambulatory infusion pump is for the delivery of insulin for the treatment of diabetes mellitus. These pumps can deliver insulin on a continuous basal basis as well as a bolus basis as is disclosed in U.S. Patent 4,498,843 to Schneider et al.

(07) The ambulatory pumps often work with a reservoir to contain the liquid medicine, such as a cartridge or syringe, and use electro-mechanical pumping or metering technology to deliver the medication to the patient via tubing from the infusion device to a needle that is inserted transcutaneously, or through the skin of the patient. The devices allow control and programming via electromechanical buttons or switches located on the housing of the device, and accessed by the patient or clinician. The devices include visual feedback via text or graphic screens, such as liquid crystal displays known as LCD's, and may include alert or warning lights and audio or vibration signals and alarms. The device can be worn in a harness or pocket or strapped to the body of the patient.

(08) Currently available ambulatory infusion devices are expensive, difficult to program and prepare for infusion, and tend to be bulky, heavy and very fragile. Filling of these devices or their reservoirs can be difficult and require the patient to carry both the intended medication as well as filling accessories when traveling or even just going to work. The accuracy and safety requirements of these devices are extremely important, based both on the medicine being delivered and the condition of the patient. Therefore, the devices require specialized care, maintenance and cleaning to assure proper functionality and safety for their intended long term use. The devices are usually sold for $4,000 to $6,000 requiring

access tool, a dispenser for causing fluid from a reservoir to flow to the exit port assembly, a local processor connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based on flow instructions from a separate, remote control device, and a wireless receiver connected to the local processor for receiving the flow instructions from a separate, remote control device and delivering the flow instructions to the local processor. The device also includes a housing containing the exit port assembly, the dispenser, the local processor, and the wireless receiver. The housing is free of user input components for providing flow instructions to the local processor in order to reduce the size, complexity and costs of the device, such that the device lends itself to being disposable in nature.

(13) According to one aspect of the present invention, the flow instructions cause a predetermined rate of fluid flow for a predetermined period. According to another aspect, the predetermined rate of fluid flow comprises a basal rate.

(14) According to another aspect of the present invention, the flow instructions cause a predetermined volume of fluid to flow for a predetermined period. According to an additional aspect, the predetermined volume comprises a bolus volume.

(15) According to an additional aspect, the device includes a least one user interface component accessible from an exterior of the housing for causing a predetermined volume of fluid to flow for a predetermined period, independently of the local processor. According to a further aspect, the device includes a least one user interface component accessible from an exterior of the housing for occluding flow to the exit port assembly.

(16) According to another aspect of the present invention, the device includes a power supply connected to the local processor. According to an additional aspect, the device includes a transmitter connected to the local processor for transmitting information from the local controller to a separate, remote control device. According to still a further aspect, the housing is free of user output components for providing information from the local processor. According to a further aspect, the exit port assembly includes a tubular member for transcutaneously entering a patient. According to still a further aspect, the device includes a reservoir.

(17) The present invention also provides a system including a fluid delivery device as described above, and further including a separate, remote control device including a remote processor, user input components connected to the remote processor for allowing a

(24) Fig. 3b is an enlarged sectional view of the dispenser for the device of Fig. 3, shown with the accumulator filled and ready to dispense a pulse of fluid upon an outlet valve being opened;

(25) Fig. 4 is a sectional side view of a third exemplary embodiment of a fluid delivery device in accordance with this invention;

(26) Fig. 4a is an enlarged sectional side view of a reservoir chamber of the device of Fig. 4;

(27) Fig. 4b is an enlarged bottom plan view of a portion of the reservoir chamber of the device of Fig. 4;

(28) Fig. 5 is a sectional side view of a fourth exemplary embodiment of a fluid delivery device in accordance with this invention;

(29) Fig. 5a is a bottom plan view of the device of Fig. 5;

(30) Fig. 6 is a sectional side view of a fifth exemplary embodiment of a fluid delivery device shown positioned on an outer surface of skin and subcutaneous tissue of a patient;

(31) Fig. 6a is a bottom plan view of the device of Fig. 6;

(32) Fig. 7 is a sectional side view of a sixth exemplary embodiment of a fluid delivery device in accordance with the present invention;

(33) Fig. 8 is a sectional side view of a seventh exemplary embodiment of a fluid delivery device in accordance with the present invention;

(34) Fig. 8a is a top plan view of the device of Fig. 8;

(35) Fig. 9 is a sectional side view of an eighth exemplary embodiment of a fluid delivery device in accordance with the present invention;

(36) Fig. 9a is a perspective view of an infusion set compatible with an outlet assembly of the device of Fig. 9;

Detailed Description of the Preferred Embodiments

(48) Set forth hereinbelow are detailed descriptions of certain embodiments and examples of fluid delivery devices, systems and kits, constructed in accordance with the present invention, as well as methods for using the devices, systems and kits. The types of liquids that can be delivered by the fluid delivery devices, systems and kits of the present invention include, but are not limited to, insulin, antibiotics, nutritional fluids, total parenteral nutrition or TPN, analgesics, morphine, hormones or hormonal drugs, gene therapy drugs, anticoagulants, analgesics, cardiovascular medications, AZT or chemotherapeutics. The types of medical conditions that the fluid delivery devices, systems and kits of the present invention might be used to treat include diabetes, cardiovascular disease, pain, chronic pain, cancer, AIDS, neurological diseases, Alzheimer's Disease, ALS, Hepatitis, Parkinson's Disease or spasticity.

(49) In Fig. 1, there is illustrated, generally at 10, a fluid delivery device according to the invention. The device 10 generally includes an exit port assembly 70 adapted to connect to a transcutaneous patient access tool, a dispenser 40 for causing fluid from a reservoir 30 to flow to the exit port assembly, a processor or electronic microcontroller (hereinafter referred to as the "local" processor) 50 connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based on flow instructions from a separate, remote control device (an example of which is shown in Fig. 2), and a wireless receiver 60 connected to the local processor for receiving the flow instructions from the separate, remote control device and delivering the flow instructions to the local processor. The device also includes a housing 20 containing the exit port assembly 70, the dispenser 40, the local processor 50, and the wireless receiver 60. The housing 20 is free of user input components, such as external buttons connected to the processor 50, for providing flow instructions to the local processor 50 in order to reduce the size, complexity and costs of the device 10, such that the device lends itself to being small and disposable in nature.

(50) In the exemplary embodiment of Fig. 1, the device 10 also includes a reservoir 30 contained within the housing 20 and connected to the dispenser 40. The reservoir 30 is provided with a collapsible design such as a metal bellows or is made of a collapsible material such as a silicone elastomer. The volume of the reservoir 30 is chosen to best suit the therapeutic application of the fluid delivery device 10 impacted by such

its own processor (hereinafter referred to as the "remote" processor) connected to the membrane keypad 120 and the LCD 110. The remote processor is programmed to receive the user inputs from the membrane keypad 120 and translate the user inputs into "flow" instructions for transmission to the fluid delivery device 10, and is programmed to send user outputs to the LCD 110.

(55) A user, such as a patient or a clinician, can thus program the fluid delivery device 10 by entering information into the remote control device 100, which then downloads information to the receiver 60 of the device 10 with each key stroke or button pressed or in a batch mode of multiple key strokes. Complex flow algorithms, requests for bolus delivery and other desired infusions of the medicinal fluid can be accomplished by entering information into the remote control device 100, which is then transmitted to the fluid delivery device 10. The communication can be confirmed as acceptable by the local processor 50 of the fluid delivery device 10 by using one or more features such as standard handshaking protocols, redundant transmissions and other communication confirmation methods, as are known to those skilled in the art.

(56) The lack of user interfaces, such as electromechanical switches on the fluid delivery device 10, results in substantial reductions in the cost, the size, and the weight of the device 10. The lack of user interfaces also allows the housing outer surface 21 of the device 10 to be relatively smooth, thereby simplifying cleaning and preventing jewelry or clothing items such as sweaters from catching on the device. Since the remote control device 100 also includes a visual display 110, the fluid delivery device 10 can be void of an information screen, further reducing cost, size and weight. Lack of user interfaces, such as electromechanical switches and information screens, greatly simplifies the design of the fluid delivery device 10 and allows the device 10 to be made more flexible and resistant to damage.

(57) Fig. 3 shows another exemplary embodiment of the fluid delivery device 10 of the present invention wherein the reservoir 30 is made of a flexible material and is enclosed in a reservoir chamber 35, which can be defined by the housing 20 and housing reservoir walls 27. The flexible reservoir 30 is placed in compression by a compressing member 33 and compressing springs 34, which are positioned between the compressing member 33 and the housing 20. The compressed, flexible reservoir 30 causes fluid inside the reservoir 30 to be at a pressure above atmospheric pressure. In a preferred embodiment,

fluid delivery device 10 one time only, such as by having the Luer connection break off when the syringe is removed.

(61) The dispenser 40 is connected in fluid communication with the reservoir 30. When the device 10 is provided with a pressurized reservoir 30, as shown in exemplary embodiment of Fig. 3, the dispenser can include an inlet valve 41 connected to the reservoir, and outlet valve 42 connected to the exit port assembly 70, and an accumulator 43 connected between the inlet valve and the outlet valve. Since the fluid in the reservoir 30 is maintained at a pressure above atmospheric pressure, opening of the inlet valve 41 allows the accumulator to fill to the reservoir pressure, after which the inlet valve is 41 is closed. At the proper time, as determined by the local processor 50 programming and instructions received from the remote control device, the outlet valve 42 can be opened to dispense fluid to the exit port assembly 70, which is at the pressure of the patient, or atmospheric pressure. The accumulator 43 will then be at atmospheric pressure, and the outlet valve 42 can be closed, ready for another repeat cycle.

(62) The dispenser 40 of the exemplary embodiment of Figure 3 does not create a driving or pumping force on the fluid passing therethrough, but rather acts as a metering device, allowing pulses of fluid to pass from the pressurized reservoir 30, through the dispenser 40, to the exit port assembly 70 at atmospheric pressure. The inlet valve 41 and the outlet valve 42 of the dispenser 40 are controlled by the local processor 50, which includes electronic programming, controls and circuitry to allow sophisticated fluid delivery programming and control of the dispenser 40.

(63) Fig. 3a shows the dispenser 40 with the accumulator 43 at atmospheric pressure. An accumulator membrane 44 is shown in its non-distended state, caused by atmospheric pressure only. Inlet valve 41 is closed, and outlet valve 42 may be open or closed, but must have been opened since the last time inlet valve 41 was opened. Fig. 3b shows the condition where outlet valve 42 is closed, and inlet valve 41 has been opened. Because of the elevated pressure of the fluid from the reservoir 30, the accumulator membrane 44 is distended, thus increasing the volume of accumulator 43 by an accumulator volume 45. After the inlet valve 41 is closed, the outlet valve 42 can be opened, to dispense the accumulator volume 45 and allow the accumulator membrane 44 to retract to the position shown in Fig. 3a.

communication standards and protocols. The information transferred includes codes or packets of codes that the local processor 50 uses to confirm that the information was received correctly, similar to the way standard telephone modem communication is performed. More sophisticated codes can be included to allow the information to be self-corrected or pinpoint the area of bad information. In an even more preferred embodiment, the communication element 60 is a two-way communication element, including a receiver and a transmitter, for allowing the fluid delivery device 10 to send information back to the remote control device 100. In such an embodiment, the remote control device 100 also includes an integral communication element 60 comprising a receiver and a transmitter, for allowing the remote control device 100 to receive the information sent by the fluid delivery device 10.

(68) The power supply 80 can be integrated into the fluid delivery device 10 and not accessible to a user. In an alternative embodiment, however, the power supply 80 can be replaceable, e.g., a replaceable battery. In another embodiment, the power supply 80 can comprise an integrated battery or capacitor, for low power components of the device 10 such as the electronic memory, and a user-inserted battery for powering the remainder of the device 10. Other components that may require electrical energy are the communication element 60, the dispenser 40, and other components such as sensors or transducers.

(69) As shown in Fig. 3, the device can include sensors or transducers such as a reservoir volume transducer 37. A similar transducer is described in U.S. Patent 5,533,389 to Kamen et al. Fig. 3 also shows a pressure transducer 221, located on the housing reservoir walls 27 and in contact with a portion of the reservoir 30. The pressure transducer 221 may consist of force sensing resistor technology such as that manufactured by Interlink, Inc. of Camarillo, CA. Reservoir transducer 37 or pressure transducer 221 can transmit information to local processor 50 to indicate how and when to activate the dispenser 40, or to indicate other parameters determining flow, as well as conditions such as the reservoir 30 being empty or leaking, or the dispensing of too much or too little fluid from the reservoir, etc.

(70) Fig. 4 shows another exemplary embodiment of the fluid delivery device 10 including an elastic sock 36 for compressing the reservoir 30 to a pressure above atmospheric pressure. The reservoir sock 36, constructed of an elastic material, has a very small unexpanded internal volume, no larger than the volume of reservoir 30 in its empty

maintain patency of the transcutaneous fluid path by flowing an inert substance at a more frequent rate then the intended infusion of the fluid in the main reservoir 30.

(74) Referring also to Fig. 5a, the device also includes a transcutaneous patient access tool comprising transcutaneous micropenetrators 75 connected to the exit port assembly 70. The transcutaneous micropenetrators 75 include a series of micro-needles or other micropenetrators that allow fluid to transcutaneously enter the body of the patient without standard needles. Similar transcutaneous micropenetrators are shown, for example, in U.S. Patent 5,983,136 to Kamen et al.

(75) The device 10 further includes an adhesive layer 201 on the outer surface 21 of the housing 20 for securing the device 10 directly to the skin of a patient. The adhesive layer is preferably provided in a continuous, oval shape encircling the exit port assembly 70 in order to provide a protective seal around the penetrated skin. The housing adhesive layer 201 can consist of material such as that used in bandages or electro surgery return pads such as those manufactured by the Valley Lab division of Tyco/U.S. Surgical.

(76) Figs. 6 and 6a show another exemplary embodiment of the fluid delivery device 10 including a housing 200 having a recessed surface 29 for creating an air pocket between the fluid delivery device 10 and the skin 210 of a patient. The device 10 also includes a secondary adhesive layer 202 attached to the first adhesive layer 201, which is attached to the bottom surface of the housing 200 surrounding the recessed surface 29. The secondary adhesive layer 202 allows the device 10 to be attached, removed and attached again to a patient. When first attached, the secondary adhesive layer 202 adheres to the skin 210. Upon removal of the device 10, the secondary adhesive layer 202 can be removed from the first adhesive layer 201, and the fluid delivery device 10 can then be reattached to the skin 210 using the adhesive layer 201.

(77) A needle connection tubing 73 terminating in a skin penetrating cannula 72 is shown connected to the exit port assembly 70. The needle connection tubing 73 is flexible, allows various placements and can be reinforced to prevent kinking. Reinforcement can be accomplished through choice of materials and ratio of wall thickness to inner diameter, or the tubing 73 can be reinforced with an internal wire coil. The skin penetrating cannula 72 can be a rigid member, such as a needle, or can be flexible. The skin penetrating cannula 72 is inserted through the skin 210 prior to attaching the fluid delivery

from the fluid delivery device 10 via the communication element 60. Alternatively, antenna 61 may be integrated into electronic module 300.

(81) The device of Fig. 8 includes an alarm transducer 223, such as a beeper or vibration device, which is also integrated into the electronic module 300. The electronic module 300 is shown encapsulated by an electronic module housing 301, which is a portion of the housing 20. The electronic module housing 301 can easily be made to be waterproof, potentially by encapsulating the entire assembly in potting material, and can be protected with shielding material or coating for the electronic module 300 to resist electromagnetic interference and electrostatic discharge without having to encapsulate the entire internal portion of the fluid delivery device 10. Alternatively, the housing 20, in the portion surrounding the electronic module 300 can be shielded or made waterproof, potentially by using a gasket material. The optional antenna 61, which can be included internal or external to the shielding material, is shown as external. The electronic module 300 may include a microprocessor, logic circuitry, read only memory, writeable memory, random access memory, analog to digital conversion circuitry, a multiplexer, the power supply 80, resistors, capacitors, semiconductor components, programmable gate arrays, operational amplifiers and various other analog and digital electronic components.

(82) Fig. 8a shows a transparent window 22 included in the housing 20 of the fluid delivery device 10 of Fig. 8, which allows a user to visually inspect the reservoir 30. Also shown is an information barcode 26, which has information that can be read by a remote control device 100 provided with a barcode scanner. Information on the barcode 26 can include amount, type and concentration of drug contained in the reservoir, the device manufacturer and serial number, and expiration dates, and various other pieces of information relative to infusion of liquid medicines into mammalian patients.

(83) Fig. 9 shows another exemplary embodiment of the fluid delivery device 10 which includes a housing 200 having flexible hinged sections 23 that allow the fluid delivery device 10 to flex during patient movement to prevent detachment and aid in patient comfort. The hinged sections 23 run along the length of the housing 20 and allow the fluid delivery device 10 to have flex along each axis of the hinged sections 23. Directions of the axes of the hinged sections 23 can be varied to provide optimum flexibility for various patient contours and areas of placement.

100. Described here is an embodiment 10 wherein the user can press a mechanical bolus button 180 to release the bolus of the intended medicine.

(87) As also shown in Fig. 11a, the bolus button 180 is t-shaped and protrudes through the housing 20. The button 180 is maintained in a deactivated position through the force of bolus button spring 181 positioned between the bolus button 180 and an internal portion of the housing 20. The bolus button 180 is attached to a bolus release finger 183 via a pivoting bolus lever 187. The bolus lever 187 has a pivot 182 attached to the housing 20, and moves the bolus release finger 183 away from a bolus delivery tubing lumen 186 and a bolus button stop 28 of the housing when the bolus button 180 is depressed against the spring 181. The bolus delivery tubing 186 is in fluid communication with the exit port tubing lumen 74 and, thus, the exit port assembly 70. When bolus button 180 is not pressed, the bias from bolus button spring 181 causes the bolus release finger 183 to press against bolus delivery tubing lumen 186 which presses against the bolus button stop 28 to occlude the bolus delivery tubing lumen 186.

(88) In order to deliver a fixed amount of fluid when the bolus button 180 is pressed, a bolus flow restrictor 184 and a bolus volume accumulator 185 are provided in the bolus delivery tubing 186. The bolus flow restrictor 184 acts as a flow limiter to prevent free flow of fluid from the reservoir 30, and creates a minimum lock-out period between full bolus volumes. Assuming in this particular embodiment that the reservoir 30 is maintained at a pressure above atmospheric pressure, the flow rate of the flow restrictor 184 is chosen to be much slower than the rate at which the bolus volume should be delivered.

(89) The bolus volume accumulator 185 expands with the inflow of fluid from the flow restrictor 184 as long as the bolus release finger 183 is occluding the bolus delivery tubing 186. The amount of expansion of the bolus volume accumulator 185 equals the bolus volume to be delivered. When the bolus button 180 is depressed, the bolus volume of fluid maintained in the bolus volume accumulator 185 is dispensed through the bolus delivery tubing lumen 186 and out of the exit port assembly 70.

(90) The time to dispense the bolus dose should be short since there are no downstream flow restrictors, and the user could be instructed to hold the button down for a required time, not more than a few seconds. Alternative designs could latch the bolus button 180 for a specific amount of time only, as the button must be released to prevent

connection to the device via wireless or hardwired communication means, to perform a transfer of information.

(93) The visual display 110 can also include information such as warning and alarm conditions based on the status of the fluid delivery device 100. Elements such as indicator lights, buzzers, and vibrational alarms may also be included in the remote control device 100 as alternative or redundant means for communicating information to the user.

(94) The user can get information and adjust the programming of the device by depressing various electromechanical switches also mounted on controller housing 102. These switches may be joined in a bank of switches and included in membrane keypad 120 as shown in Figs. 11 and 11a and as is common with hand held electronic devices. It is preferred that the choice of electromechanical switches of the membrane keypad 120 interface with the visual display 110 in a menu driven fashion making reading information and programming the device more user friendly for the user. In an alternative embodiment, the visual display 110 and membrane keypad 120 can be combined into a single device such as a touch screen display, also common to electronic devices. Combination of touch screen displays, membrane keypads and singular switches may all be integrated into the remote control device 100.

(95) The remote control device 100 may include various electromechanical jacks, which can accept electromechanical plugs from various devices. Shown in the figure are three plugs, a bar code reader 140, a glucometer port 150 and a computer port 170. These ports can allow two way transfer of information to enhance the capabilities of remote control device 100 and improve its user friendliness. Fig. 12a shows a schematic cross section of the remote control device 100. The membrane keypad 120 and visual display 110 are attached to the controller electronics 105. Depicted is glucometer port 150 attached to the controller electronics 105. Bar code reader 140 and computer port 170 are also attached to the controller electronics, not shown. The controller electronics are mounted and soldered to the controller printed circuit board 101 as is the controller communication element 160.

(96) The controller communication element 160 is designed to transmit signals, or information to the communication element 60 of the fluid delivery device 10. The controller electronics 105 act as a "translator" in translating user inputs received through the

the upgraded device. The embedded program may be contained in read only memory, or ROM, while the downloaded program can be written into electronically writeable memory. The automatic update feature, available for each device to upgrade the other, is another way to make sure the user has the best available product for use.

(99) Another advantageous feature associated with two way communication is the addition of a proximity alarm. The design of the fluid delivery device 10 and remote control device 100 electronics can be such that when the distance between the two devices is greater than a particular radial length, one or both of the devices will alert the user, potentially with an audio alarm. The alarming distance should be chosen so that it is less than the maximum communication range of the two devices. A method of creating the alarm is for the fluid delivery device 10 to send out frequent packets of information at a predetermined rate and at an amplitude or power less than the normal communication power, providing a safety margin for the proximity detection. The remote control device 100 is programmed to expect to receive this communication at the predetermined rate, and lack of receipt of one or more of these packets, causes the remote control device 100 to activate its audio alarm 106. Alternatively or additionally, a vibrational alarm may be included. Proximity alarms may be included that do not require two way communication, by integrating a device such as a magnet into the housing 20 of fluid delivery device 10, and integrating magnetic field detection means into the remote control device 100. When the magnetic field detection means of the remote control device 100 do not detect the presence of the magnetic field of the fluid delivery device 10, the remote control device 100 activates the controller audio alarm 106.

(100) The remote control device 100 includes a controller power supply 108 that powers the various electronic components including the controller electronics 105, controller audio alarm 106. The controller power supply 108 may be a standard battery and in the preferred embodiment, the power supply 108 may be replaceable by the user by removing a battery door, not shown, and replacing after power supply 108 is inserted and attached. In an alternative embodiment, the power supply is integrated into the remote control device 100, and can be recharged with a separate device or contains enough power to supply the device for its intended length of use.

(101) The fluid delivery device 10 of the present invention may be sold to hospitals, pharmacies, outpatient centers or the patients themselves. If the fluid delivery

must be read prior to programming or otherwise using the fluid delivery device 10. This feature can greatly reduce programming errors such as those associated with the patient entering drug information. If the patient were to enter a drug concentration that was incorrect, and did all the remaining programming in units of drug, instead of volume, which is common practice, while the device would function properly, all of the volumes delivered would be inaccurate based on the ratio of the incorrect concentration entered versus the true concentration of the drug being delivered. Many drugs are available in multiple concentrations such as insulin often made available to patients in 40, 50 and 100 units per ml concentrations.

(105) Fig. 13a shows the remote control device 100 of the present invention that could be packaged or provided as a kit with one or more of sterile package assembly 350, including at least one fluid delivery device 10. There is no need for the remote control device 100 to be sterilized, so if the fluid delivery device 10 was sterilized, one or more sterile package assembly 350 can be boxed or otherwise packaged with a single remote control device 100 along with one or more other devices 10.

(106) Fig. 13b shows a therapeutic fluid supply 250, which may consist of a vial of drug such as insulin. The drug, in one or more vials, which has been sterilized and made otherwise biocompatible for use, can be packaged with one or more sterile package assemblies 350 as well as with one or more remote control devices 100. Additional devices may be included in the kit if desired.

(107) Fig. 13c shows a sterile infusion set assembly 407 including the transcutaneous infusion set 400 described hereinabove packaged in an infusion set pouch 406. The infusion set 400 includes an infusion set Luer 401 connected to infusion set flexible tubing 404 and terminating in an infusion set penetrating cannula 405. An optional set of infusion set wings 403 can be included to attach the infusion set 400 to the patient's skin. In the preferred embodiment of fluid delivery device 100, the transcutaneous delivery means are integrated into exit port assembly 70, however in an alternative embodiment, the exit port assembly 70 can be attached to infusion set 400. In this particular embodiment, it may be desirable to kit sterile infusion set assemblies 407 with any quantity of one or more of the sterile assembly packs 350, the fluid delivery device 10, the remote control device 100 or the therapeutic fluid supply 250.

sterilization and packaging of part or all of the fluid delivery device 10 and therapeutic fluid have also been described.

(111) Although exemplary embodiments of the invention have been shown and described, many changes, modifications and substitutions may be made by those having ordinary skill in the art without necessarily departing from the spirit and scope of this invention. For example, the fluid delivery device of this invention is intended to be low cost, light weight, simple to use and potentially disposable by removing a majority of the user interface, including electromechanical switches, from the fluid delivery device, and including a separate controller to replace those functions. A reservoir, fluid dispenser, transcutaneous fluid administration means, solid state electronics and wireless communications are included in the fluid delivery device to perform its intended function. While various means for reservoir construction, pressurization means, fluid pumping means, fluid metering means, transcutaneous delivery, electronic control and wireless communications have been discussed in this application, alternatives to each of these areas can be made without departing from the spirit of the invention.

(112) In addition, where this patent application has listed the steps of a method or procedure in a specific order, it may be possible (or even expedient in certain circumstances) to change the order in which some steps are performed, and it is intended that the particular steps of the method or procedure claims set forth hereinbelow not be construed as being order-specific unless such order specificity is expressly stated in the claim.

7. A device according to Claim 1, further comprising at least one user interface component accessible from an exterior of the housing for occluding flow to the exit port assembly.

8. A device according to Claim 1, further comprising a power supply for supplying electrical power to the local processor.

9. A device according to Claim 8, wherein the power supply is integrated with the device.

10. A device according to Claim 8, wherein the power supply comprises a replaceable battery.

11. A device according to Claim 1, wherein the receiver utilizes radio frequency signals.

12. A device according to Claim 1, further comprising a transmitter connected to the local processor for transmitting information from the local processor to a separate, remote control device.

13. A device according to Claim 12, wherein the housing is free of user output components for providing information from the local processor.

14. A device according to Claim 1, wherein the exit port assembly includes a Luer connector.

15. A device according to Claim 1, further comprising a transcutaneous patient access tool connected to the exit port assembly.

16. A device according to Claim 15, wherein the transcutaneous patient access tool comprises a tubular member.

17. A device according to Claim 16, wherein the tubular member is adapted for residing in subcutaneous tissue of a patient.

18. A device according to Claim 17, wherein the tubular member comprises a rigid needle.

30. A device according to Claim 1, wherein the dispenser comprises a pump for pumping fluid from a reservoir to the exit port assembly.

31. A device according to Claim 1, further including at least one sensor connected to the local processor and comprising at least one of an occlusion detector, a reservoir volume transducer, a reservoir empty detector, a leak detector, a pressure transducer, a fluid contact detector, an impedance monitor, a voltage detector, a photodetector, and a vibration monitor.

32. A device according to Claim 1, further comprising an alarm connected to the local processor.

33. A device according to Claim 1, further comprising adhesive on an exterior of the housing.

34. A device according to Claim 33, wherein the adhesive is provided in at least one continuous band surrounding the exit port assembly.

35. A device according to Claim 1, wherein the exit port assembly is mounted in a recessed portion of the housing.

36. A device according to Claim 1, wherein the housing is flexible.

37. A device according to Claim 36, wherein the housing includes hinge sections.

38. A device according to Claim 1, wherein the housing includes a window.

39. A device according to Claim 1, wherein the housing includes vent holes.

40. A device according to Claim 1, wherein the local processor and the receiver are encapsulated in an electromagnetic shielding material.

41. A device according to Claim 40, wherein the receiver includes an antenna extending out of the electromagnetic shielding material.

42. A device according to Claim 1, wherein the local processor includes programming which can be updated by a remote control device.

a housing containing the exit port assembly, the dispenser, the local processor, and the wireless transmitter;

wherein the housing is free of user output components for providing the flow information from the local processor to a user.

49. A device according to Claim 48, wherein the local processor is programmed to receive at least some of the flow instructions from a separate, remote control device, and the device further includes a wireless receiver connected to the local processor for receiving the flow instructions from a separate, remote control device and delivering the flow instructions to the local processor.

50. A system including a fluid delivery device according to Claim 48, and further comprising a remote control device separate from the fluid delivery device and including:

a remote processor;

user output components connected to the remote processor for allowing a user to receive flow information, and

a receiver connected to the remote processor for receiving the flow information from the transmitter of the fluid delivery device.

51. A system for delivering a fluid to a patient, comprising:

a) a fluid delivery device for attachment to a skin surface of a patient and including,

an exit port assembly adapted to connect to a transcutaneous patient access tool,

a dispenser for causing fluid from a reservoir to flow to the exit port assembly,

a local processor connected to the dispenser and programmed to cause a flow of fluid to the exit port assembly based at least in part on received flow instructions, and further programmed to provide flow information,

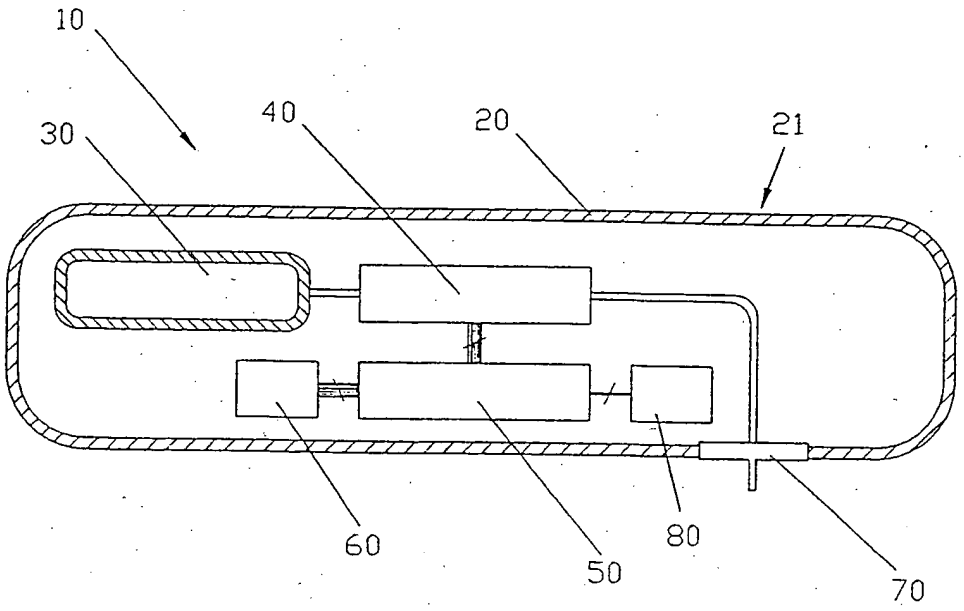

Fig. 1

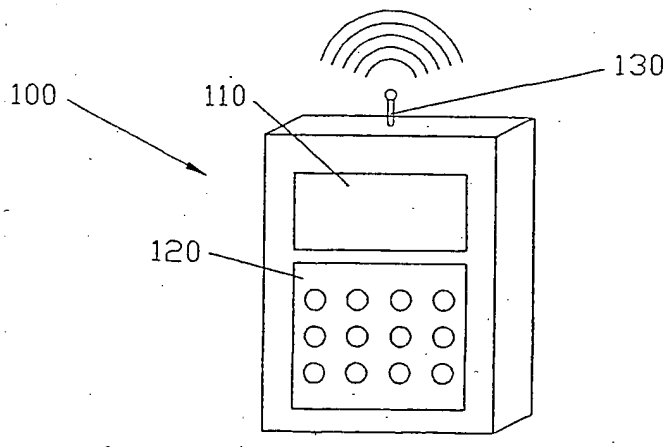

Fig. 2

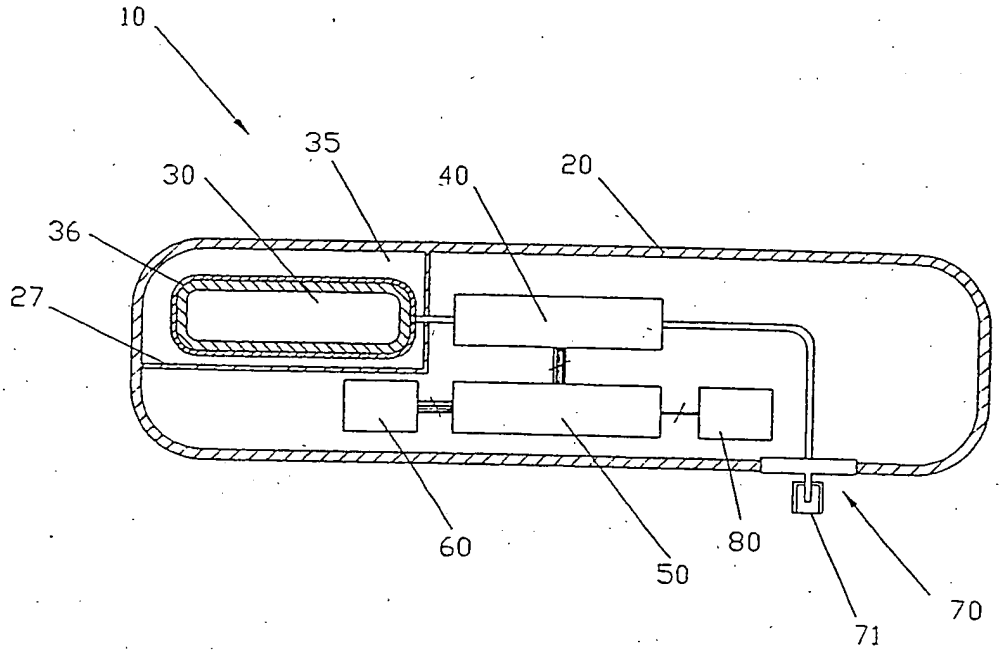

Fig. 4

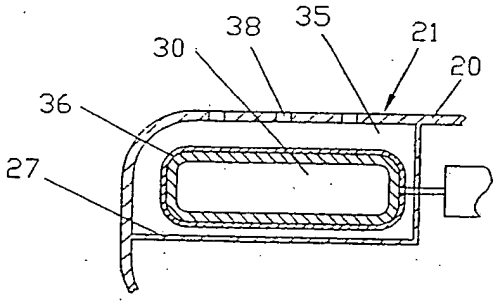

Fig. 4a

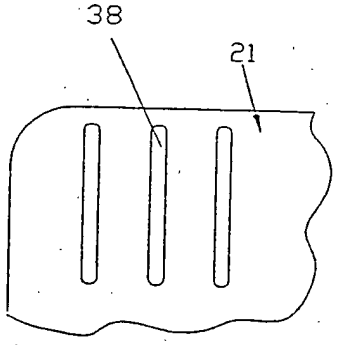

Fig. 4b

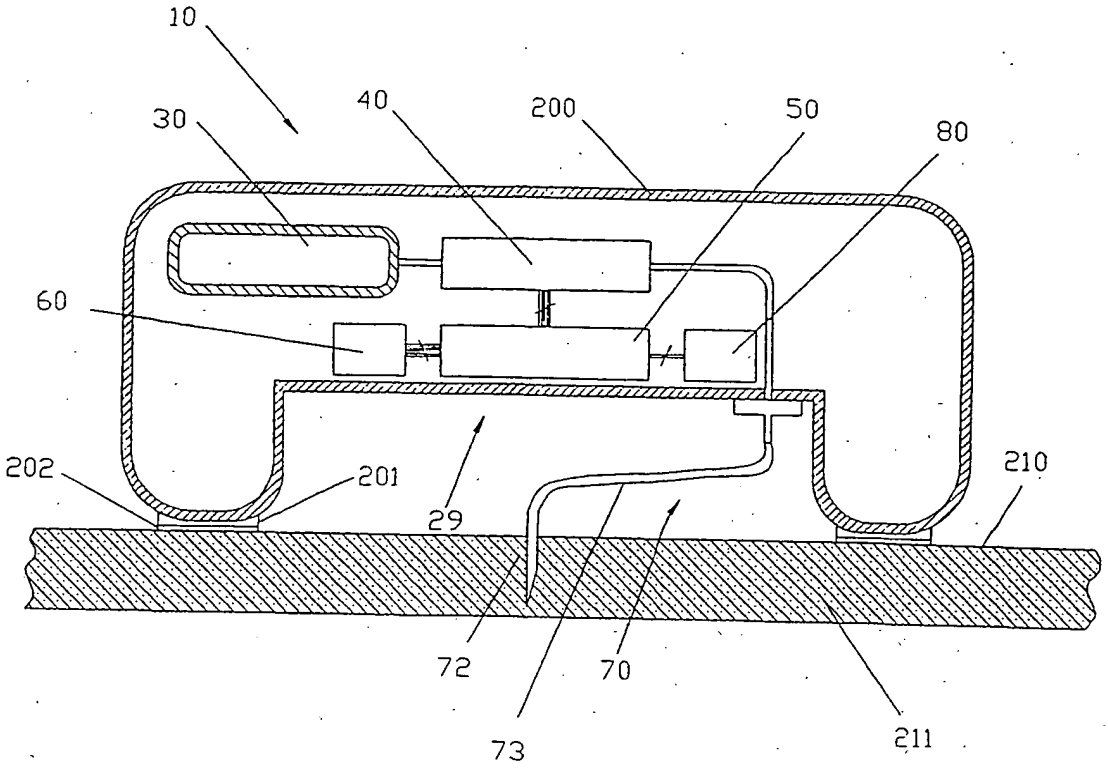

Fig. 6

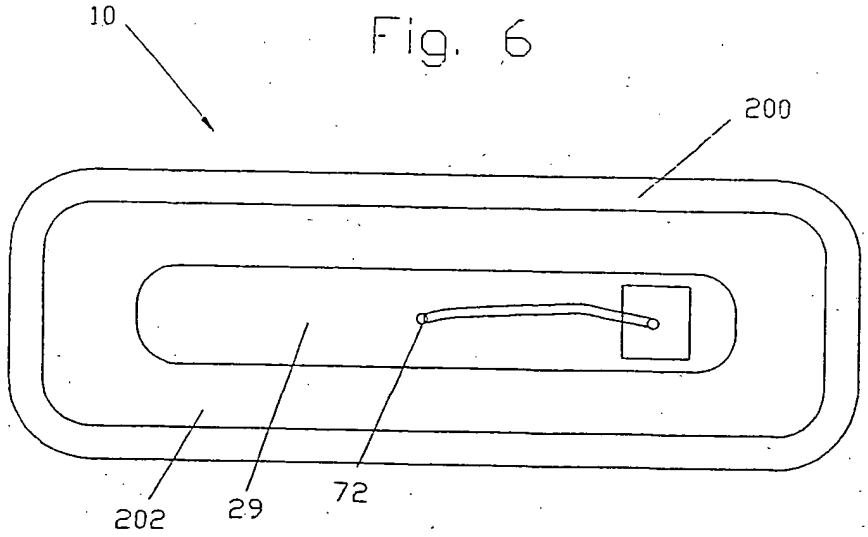

Fig. 6a

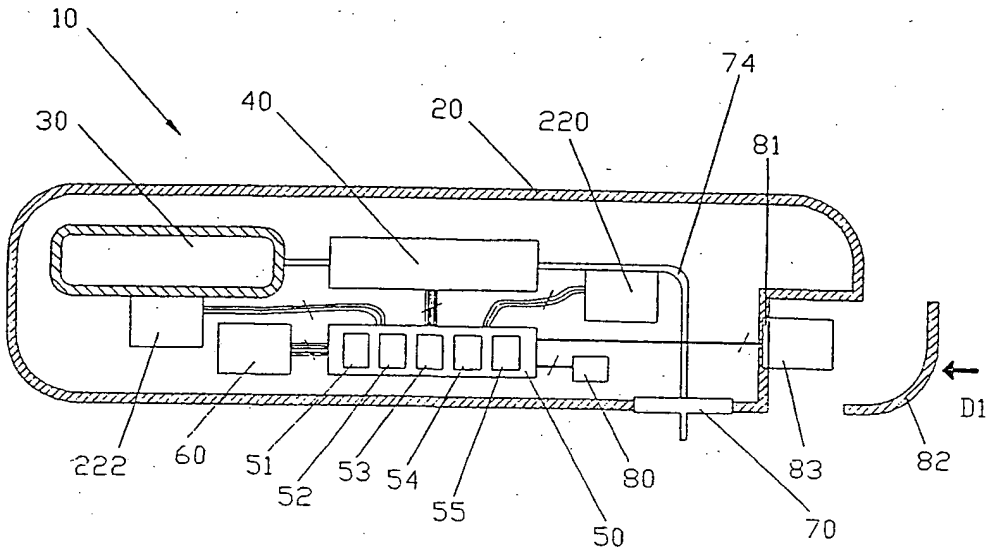

Fig. 7

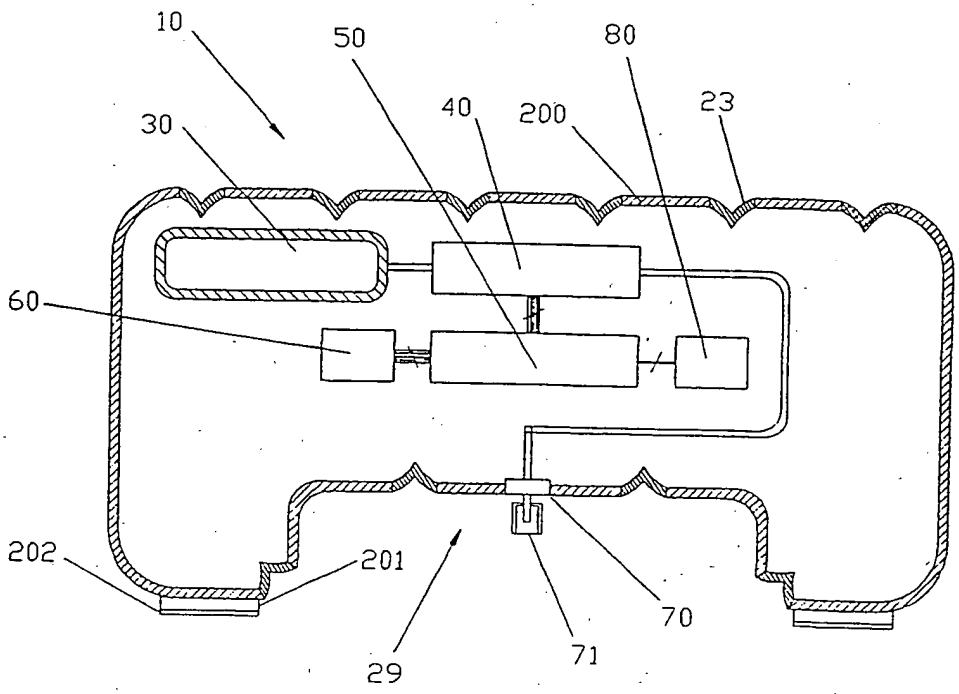

Fig. 9

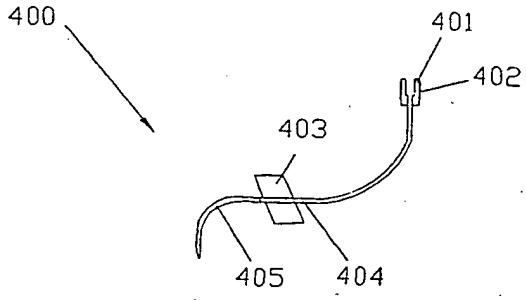

Fig. 9a

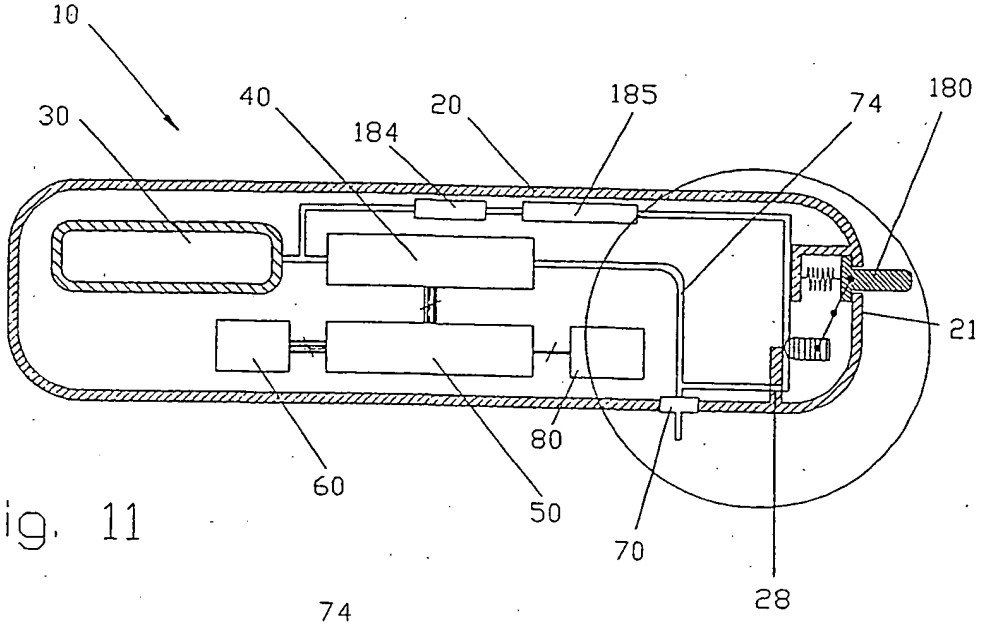

Fig. 11

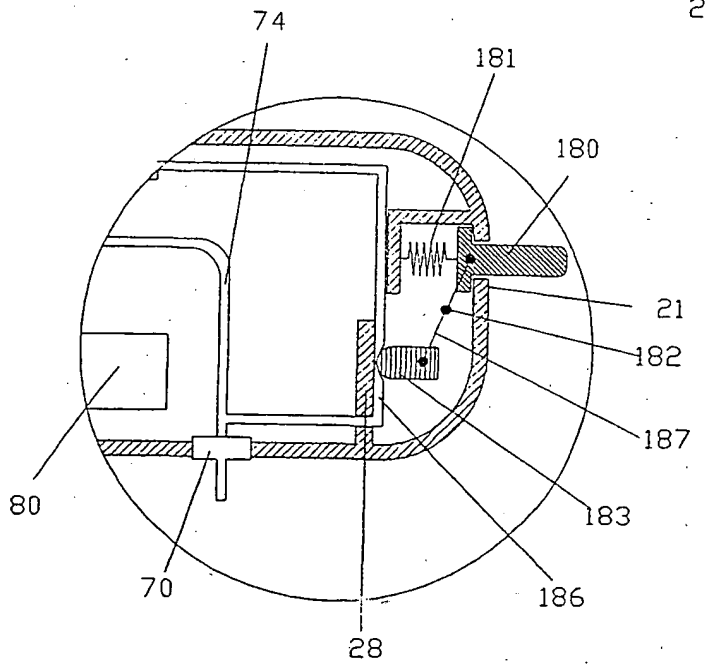

Fig. 11a

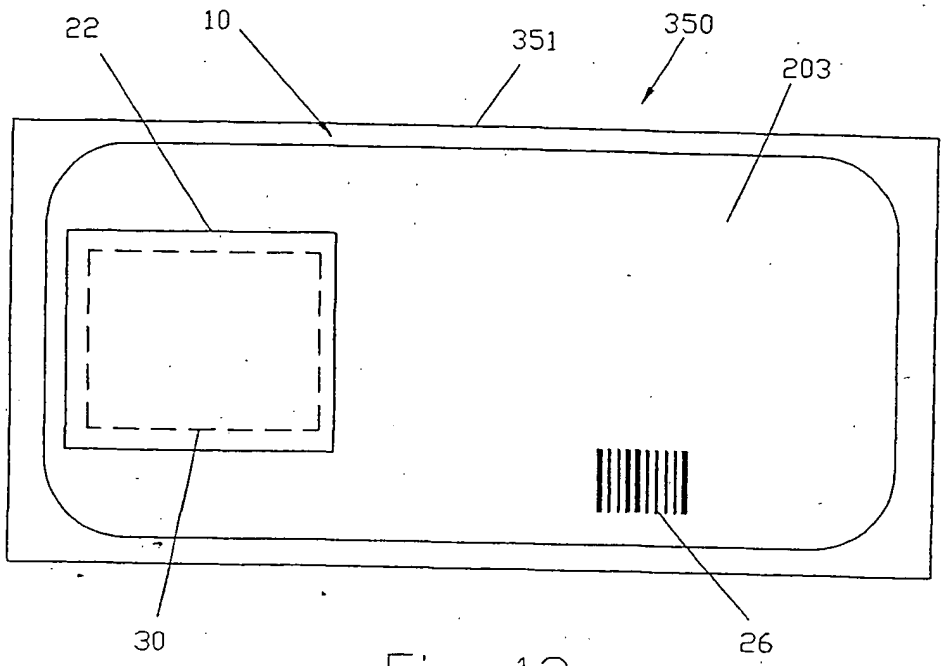

Fig. 13

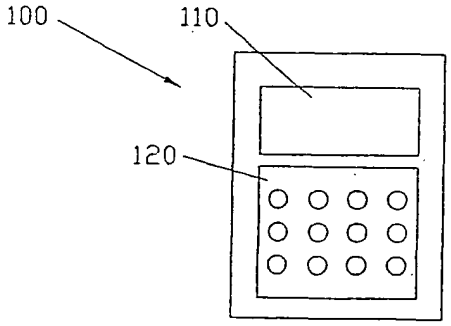

Fig. 13a

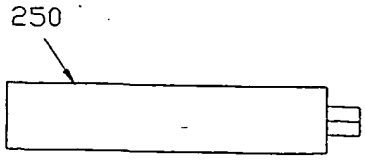

Fig. 13b

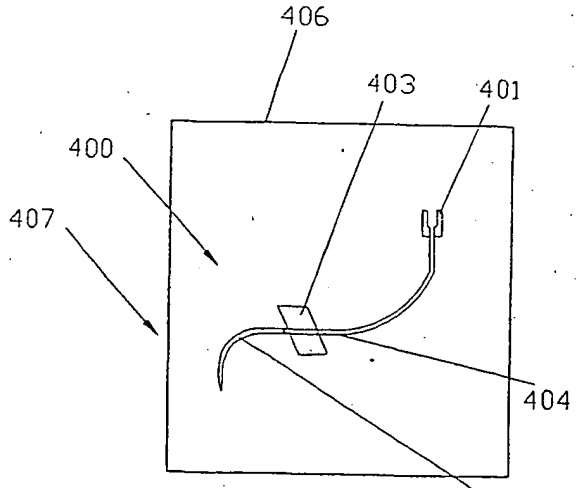

Fig. 13c